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| 10/754,922 | 01/09/2004 | Jeffrey Stavenhagen | 1301.0004C | 8663 |

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| EXAMINER | |
|---|---|
| CROWDER, CHUN | |
| **ART UNIT** | **PAPER NUMBER** |
| 1644 | |

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**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

| Office Action Summary | Application No. | Applicant(s) | |
|---|---|---|---|
| | 10/754,922 | STAVENHAGEN ET AL. | |
| | Examiner | Art Unit | |
| | Chun Crowder | 1644 | |

*-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --*

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

1)☐ Responsive to communication(s) filed on *18 July 2007*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

4)☒ Claim(s) *92-146* is/are pending in the application.

4a) Of the above claim(s) *93-95,102-104 and 115-132* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *92, 96-101, 105-114, and 133-146* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

**Application Papers**

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

## DETAILED ACTION

1. Applicant's amendment, filed on July 18, 2007, is acknowledged.

Claims 1-91 have been previously canceled.
Claims 133-146 have been added.

Claims 92-146 are pending.

Claims 93-95, 102-104, and 115-132 have been withdrawn from further consideration by the Examiner, under 37 C.F.R. 1.142(b), as being drawn to nonelected invention.

Claims 92, 96-101, 105-114, and newly added claims 133-146 are currently under consideration as they read on the originally elected invention of a polypeptide comprising a variant Fc region and species of IgG1, 396L without additional amino acid modifications, FcγRIIIA, Her2/neu, and a composition without additional agent.

2. This Office Action will be in response to applicant's arguments, filed on July 18, 2007

The rejections of record can be found in the previous Office Action, mailed on April 19, 2007.

3. Applicant's amendment to the specification, filed on July 18, 2007, has been entered.

4. Applicant's affirmation for the species election, filed on July 18, 2007, is acknowledged.

5. The amendment, filed on July 18, 2007, is considered non-compliant because it fails to meet the requirements of 37 CFR § 1.121, as amended on June 30, 2003 (see *68 Fed. Reg. 38611*, Jun. 30, 2003).

The amendment is non-compliant because each claim has not been provided with the proper status identifier. Specifically, claims 96, 97, 99, and 100 have not been amended, however, the status identifier for said claims are "currently amended"; as such, the individual status of each claim cannot be identified.

In the interest of compact prosecution, this Office Action is set forth.

Applicant is required to submit a "Listing of Claims" that is compliant with the requirements of 37 CFR 1.121.

6. In light of applicant's amendment to the claims, the previous rejection, under 35 U.S.C. 112, 2nd paragraph, has been withdrawn.

7. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

8. Claims 92, 96-101, 105-114, and newly added claims 133-137 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention for reasons of record set forth in the previous Office Action mailed on April 19, 2007.

A) The claims recite "a polypeptide comprising a variant Fc " or "at least an amino acid modification" as part of the invention.

Applicant's arguments in conjunction with the Stavenhagen declaration under 37 C.F.R. 1.132, filed on July 18, 2007, have been fully considered but have not been found persuasive.

Applicant argues that an antibody is a polypeptide comprising a variant Fc region and the instant specification discloses the make and use of antibodies; as such, applicant asserts that any polypeptide containing the claimed Fc variants is enabled.

Furthermore, the applicant argues that without the discovery of position 396, the ordinary skill in the art would not have known which of the 198 amino acid residues in the Fc region can be altered for increased binding affinity to Fcγ receptors. Furthermore, applicant argues that because of applicant's discovery that residue 396 of the Fc region can be altered to enhance the binding to Fcγ receptors, any polypeptide containing at least amino acid substitution at position 396 with enhanced binding to Fcγ receptors is enabled to one skill in the art.

This is not found persuasive for following reasons:

Contrary to applicant's assertion that antibody is a polypeptide comprising an Fc region, it is noted that "antibody" and "polypeptide" are two different terms encompassing different breadth. While the Examiner acknowledges that the specification appears to show antibodies with certain specified amino acid substitutions, nevertheless, the instant claims encompass in their breadth *any* "a polypeptide comprising a variant Fc " comprising with at least one amino acid substitutions that do not appear to have sufficient guidance and directions in the disclosure.

Further, as the Stavenhagen declaration asserts that there are 198 amino acid residues in the Fc region of an antibody, it would be undue burden for skilled artisan to determine which residues can be altered to have enhanced binding affinity to Fcγ receptors; even if position 396 was identified, it is still unpredictable to determine what other residues can be change in conjunction with position 396 for an increased binding affinity to Fcγ receptors.

Therefore, In view of the quantity of experimentation necessary, the unpredictability of the art, the lack of sufficient guidance in the specification, and the breadth of the claims, it would take undue trials and errors to practice the claimed invention.

Applicant is further reminded that the claims are read to the extent of the originally elected invention of a polypeptide comprising a variant Fc region and species of IgG1, 396L without additional amino acid modifications, FcγRIIIA, Her2/neu, and a composition without additional agent.

Applicant is once again suggested to consider amending the claimed polypeptide to antibody.

B) Claim 114 recites "pharmaceutical composition" as part of the invention.

Applicant's arguments have been fully considered but have not been found persuasive.

Applicant argues that Ex parte Aggarwall opinion was directed to the state of the art of 1984; and applicant asserts that therapeutic antibody pharmaceutical compositions are well known in the art.

This is not found persuasive for following reasons:

Contrary to applicant's assertion that Ex parte Aggarwall is not pertinent to the current state of art, it is noted that the mere age of the cited opinion is not persuasive that it cannot be applied herein.

The "pharmaceutical composition" has the intended pharmaceutical use and for the claims to enabled, the specification must teach how to make the composition without undue experimentation and must teach how to use the pharmaceutical composition without under experimentation.

Given that the specification does not appear to provide sufficient guidance and directions as how to make an antibody with at least an amino acid modification at position 396 of the Fc region as discussed above, the specification fails to discloses how to make a "pharmaceutical composition".

Further, the recited "pharmaceutical composition" has the intended uses for prevention, diagnosis or treatment of diseases in human and animals. Thus, to enable such claims, the specification must teach how to use the composition without undue experimentation for prevention, diagnosis, and treatment diseases in human and animals. However, the instant specification fails to teach how to use a "pharmaceutical composition" as claimed.

Therefore, in view of the quantity of experimentation necessary, the limited working example, the unpredictability of the art, the lack of sufficient guidance in the specification, and the breadth of the claims, it would take undue trials and errors to practice the claimed invention.

Applicant is once again suggested to delete "pharmaceutical" to obviate this rejection.

9. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

10 Claims 92, 96-101, 105-114, and newly added claims 133-146 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over: claims 1-8, 10-30, 32, 42, 55, and 57-62 of the copending USSN 11/271,140, and claims 1-13, 18-22, 29-34, 42, and 43 of the copending USSN 11/502,820 for reasons of record.

Applicant requests that the provisional double patenting rejection be held in abeyance until allowable subject matter has been identified in the instant application and USSN 11/271,140 and 11/502,820.

Given that no terminal disclaimers signed by the assignee and fully complied with 37 CFR 3.73(b) were filed, the provisional rejections on the ground of nonstatutory obviousness-type double patenting is maintained.

11. Conclusion: no claim is allowed.

12. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

13. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Chun Crowder whose telephone number is (571) 272-8142. The examiner can normally be reached Monday through Friday from 8:30 am to 5:00 pm. A message may be left on the examiner's voice mail service. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christina Chan can be reached on (571) 272-0841. The fax number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Chun Crowder, Ph.D.
Patent Examiner
August 23, 2006

Maher Haddad

MAHER M. HADDAD
PRIMARY EXAMINER